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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/307,956	05/10/1999	JAMES R. SCHNEIDER	13394	5537

7590 03/29/2002

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EXAMINER

ISABELLA, DAVID J

ART UNIT PAPER NUMBER

3738

DATE MAILED: 03/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/307,956

Applicant(s)

SCHNEIDER, JAMES R.

Examiner

DAVID J ISABELLA

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

***Continued Prosecution Application***

The request filed on 8/27/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09307956 is acceptable and a CPA has been established. An action on the CPA follows.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-20, 22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pratt (Publications Laryngoscope 96: 1986; 29<sup>th</sup> Ann. Meeting of Amer Society for Head and Neck Surgery: 1987) in view of Dardik et al.

The publications to Pratt discloses the use of freeze-dried microarterial allografts that have reduced immune response when implanted. In each of the publication, Pratt suggests that freeze dried placental vessels should be explored as microarterial allografts. It is clear from the studies by Pratt and Chow that freeze dried tissues prevent immune response. Dardik, et al teaches that placental and umbilical tissues have been used as a source for microarterial vessels for reconstructive surgery. In 1976, the current skill in the art was to chemically modify the vessels from the umbilical cord by tanning to remove surface antigens. It has been found that the tanning chemicals themselves modifies the surface of the treated vessels so as to,

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inherently, cause immune response. In light of the teachings of Dardik, et al, to use the vessels derived from placental and/or umbilical tissues as a source of microarterial allografts that can be freeze-dried to yield a reconstructive allograft that exhibits low immune response would have been obvious to one with ordinary skill in the art at the time of the invention thereof.

The limitations of the dependent claims are fully met by combination of Pratt and Dardik, et al..

Claims 21,23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pratt and Dardik as applied to claim 14 above, and further in view of Lau, et al and Chin as applied in the last office action.

Dardik, et al is silent as to the use of polyamides however Dardik, et al suggest the broad use of polyesters as the material for stent construction. Lau, et al teaches the specific use of polyamides to reinforce umbilical derived tissues. To use nylon as a stent for reinforcing the tissue of Pratt would have been obvious from the combined teachings of Dardik, et al and Lau, et al to provide a vessel with more support in vivo.

Chin teaches the use of bifurcated stent graft derived from umbilical source. To use stents in bifurcating vessels would have been obvious from the teachings of Chin as a means for providing additional vessel support in vivo.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Response to Arguments***

Applicant's arguments filed 2/08/02 have been fully considered but they are not persuasive. The articles of Pratt clearly disclose the freeze-drying of the grafts. While not entirely successful, the process was known at the time of the invention. Moreover, applicant's claims makes no distinction between the allograft of the invention as the allograft as disclosed by Pratt. The frozen graft as claimed is identical to the graft of the prior art.

Applicant arguments are not commensurate with the scope of the claims. Moreover, applicant specification, page 19, sets forth a time of two months before the vessel was examined. Obviously, the time frame of Pratt and that of applicant appears to be similar. Contrary to applicant's assertion that the examiner's position is not accurate, the scope of the claims does not preclude the combination of Pratt and Lau, et al in rendering the invention obvious. Dardik, et al is used to point out that vessels derived from Placental and Umbilical tissues have been used as a source for


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microarterial graft. Examiner is not suggesting anything more than the basic establishment that the use of tissues and some treatment of the tissues to reduce immune response would have been obvious to one with ordinary skill in the art. Examiner is not suggesting to destroy the benefits of Pratt with the method for treating the tissues as set forth in Dardik, et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703 308 3060. The examiner can normally be reached on MONDAY-THURSDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703 308 2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308 3579 for regular communications and 703 308 2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308 0868.



DAVID J ISABELLA  
Primary Examiner  
Art Unit 3738

DJI  
March 27, 2002